



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0961]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Environmental Impact Considerations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in the FDA collection of information "Environmental Impact Considerations."

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-N-0961 for "Environmental Impact Considerations." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469,

September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility;

(2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Environmental Impact Considerations--21 CFR Part 25

OMB Control Number 0910-0322—Extension

I. Background

FDA is requesting OMB approval for the reporting requirements contained in the FDA collection of information "Environmental Impact Considerations." The National Environmental Policy Act (NEPA) (42 U.S.C. 4321-4347) states national environmental objectives and imposes upon each Federal Agency the duty to consider the environmental effects of its actions. Section 102(2)(C) of NEPA requires the preparation of an environmental impact statement (EIS) for every major Federal action that will significantly affect the quality of the human environment.

FDA's NEPA regulations are in part 25 (21 CFR part 25). All applications or petitions requesting Agency action require the submission of a claim for categorical exclusion or an environmental assessment (EA). A categorical exclusion applies to certain classes of FDA-regulated actions that usually have little or no potential to cause significant environmental effects and are excluded from the requirements to prepare an EA or EIS. Section 25.15(a) and (d) specifies the procedures for submitting to FDA a claim for a categorical exclusion.

Extraordinary circumstances (§ 25.21), which may result in significant environmental impacts, may exist for some actions that are usually categorically excluded. An EA provides information that is used to determine whether an FDA action could result in a significant environmental

impact. Section 25.40(a) and (c) specifies the content requirements for EAs for non-excluded actions.

This collection of information is used by FDA to assess the environmental impact of Agency actions and to ensure that the public is informed of environmental analyses. Firms wishing to manufacture and market substances regulated under statutes for which FDA is responsible must, in most instances, submit applications requesting approval. Environmental information must be included in such applications for the purpose of determining whether the proposed action may have a significant impact on the environment. Where significant adverse events cannot be avoided, the Agency uses the submitted information as the basis for preparing and circulating to the public an EIS, made available through a *Federal Register* document also filed for comment at the Environmental Protection Agency. The final EIS, including the comments received, is reviewed by the Agency to weigh environmental costs and benefits in determining whether to pursue the proposed action or some alternative that would reduce expected environmental impact.

Any final EIS would contain additional information gathered by the Agency after the publication of the draft EIS, a copy or a summary of the comments received on the draft EIS, and the Agency's responses to the comments, including any revisions resulting from the comments or other information. When the Agency finds that no significant environmental effects are expected, the Agency prepares a finding of no significant impact.

FDA estimates the burden of this collection of information as follows:

II. Estimated Annual Reporting Burden for Human Drugs (Including Biologics in the Center for Drug Evaluation and Research)

Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for categorical exclusion under § 25.30 or § 25.31, or an EA under § 25.40. Annually, FDA receives approximately 3,687 INDs from 2,456 sponsors; 140 NDAs from 116 applicants; 3,192 supplements to NDAs from 443 applicants; 28 biologic license applications (BLAs) from 22 applicants; 464 supplements to BLAs from 52 applicants; 1,152 ANDAs from 248 applicants; and 6,774 supplements to ANDAs from 384 applicants. FDA estimates that it receives approximately 15,437 claims for categorical exclusions as required under § 25.15(a) and (d) and 10 EAs as required under § 25.40(a) and (c). Based on information provided by the pharmaceutical industry, FDA estimates that it takes sponsors or applicants approximately 8 hours to prepare a claim for a categorical exclusion and approximately 3,400 hours to prepare an EA.

Table 1.--Estimated Annual Reporting Burden for Human Drugs¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and(d)	3,724	4.1453	15,437	8	123,496
25.40(a) and (c)	10	1	10	3,400	34,000
Total					157,496

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

III. Estimated Annual Reporting Burden for Medical Devices

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for categorical exclusion under § 25.30 or § 25.34 or an EA under § 25.40. In 2017, FDA received an average of 50 claims (original PMAs and supplements) for categorical exclusions as required under § 25.15(a) and (d), and 0 EAs as required under § 25.40(a) and (c). FDA estimates that approximately 50 respondents will submit an average of 1 application for categorical exclusion annually. Based on information provided

by sponsors, FDA estimates that it takes approximately 6 hours to prepare a claim for a categorical exclusion.

Table 2.--Estimated Annual Reporting Burden for Medical Devices¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and (d)	50	1	50	6	300

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

IV. Estimated Annual Reporting Burden for Biological Products, Drugs, and Medical Devices in the Center for Biologics Evaluation and Research

Under 21 CFR 601.2(a), BLAs as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA receives approximately 34 BLAs from 18 applicants, 801 BLA supplements to license applications from 156 applicants, 345 INDs from 256 sponsors, 1 NDA from 1 applicant, 26 supplements to NDAs from 8 applicants, 1 ANDA from 1 applicant, 1 supplement to ANDAs from 1 applicant, 8 PMAs from 3 applicants, and 33 PMA supplements from 16 applicants. FDA estimates that approximately 10 percent of these supplements would be submitted with a claim for categorical exclusion or an EA.

FDA has received approximately 481 claims for categorical exclusion as required under § 25.15(a) and (d) annually and 2 EAs as required under § 25.40(a) and (c) annually. Therefore, FDA estimates that approximately 247 respondents will submit an average of 2 applications for categorical exclusion and 2 respondents will submit an average of 1 EA. Based on information provided by industry, FDA estimates that it takes sponsors and applicants approximately 8 hours to prepare a claim of categorical exclusion and approximately 3,400 hours to prepare an EA for a biological product.

Table 3.--Estimated Annual Reporting Burden for Biological Products¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and (d)	247	2	494	8	3,952
25.40(a) and(c)	2	1	2	3,400	6,800
Total					10,752

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

V. Estimated Annual Reporting Burden for Animal Drugs

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications (INADs) and generic investigational new animal drug applications (JINADs), and 21 CFR 571.1(c) food additive petitions must contain a claim for categorical exclusion under § 25.30 or § 25.32 or an EA under § 25.40. Annually, FDA's Center for Veterinary Medicine has received approximately 810 claims for categorical exclusion as required under § 25.15(a) and (d) and 22 EAs as required under § 25.40(a) and (c). Assuming an average of 10 claims per respondent, FDA estimates that approximately 81 respondents will submit an average of 10 claims for categorical exclusion. FDA further estimates that 22 respondents will submit an average of 1 EA. FDA estimates that it takes sponsors/applicants approximately 3 hours to prepare a claim of categorical exclusion and an average of 2,160 hours to prepare an EA.

Table 4.--Estimated Annual Reporting Burden for Animal Drugs¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.15(a) and (d)	81	10	810	3	2,430
25.40(a) and (c)	22	1	22	2,160	47,520
Total					49,950

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

VI. Estimated Annual Reporting Burden for Tobacco Products

Under sections 905, 910, and 911 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements (PMTAs), SEs, Exemption from SEs, and modified risk tobacco products must contain a claim for categorical exclusion or an EA. FDA's estimates are based on actual report data from fiscal year (FY) 2015 to FY 2017, on average FDA estimated it received approximately 260 premarket review of new tobacco PMTAs from 260 respondents, 3,601 provisional reports intended to demonstrate the substantial equivalence of a new tobacco product (SEs) from 3,601 respondents, 2,375 regular SE reports from 2,375 respondents, 101 exemption from substantial equivalence requirements applications (SE Exemptions) from 101 respondents, and 27 modified risk tobacco product applications (MRTPAs) from 27 respondents. Based on updated data FDA estimates 5,832 EAs from 5,832 respondents as required under § 25.40(a) and (c). A total of 5,832 respondents will submit an average of 1 application for environmental assessment. Part of the information in the EA will be developed while writing other parts of a PMTA, SE, Exemption from SE, or MRTPA. Based on FDA's experience, previous information provided by potential sponsors and knowledge that part of the EA information has already been produced in one of the tobacco product applications, FDA estimates that it takes approximately 80 hours to prepare an EA.

Table 5.--Estimated Annual Reporting Burden for Tobacco Products¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
25.40(a) and (c)	5,832	1	5,832	80	466,560

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The Estimated Annual Reporting Burden for Human Foods is no longer a part of this information collection. The burden has now been incorporated into OMB control number 0910-0541.

Our estimated burden for the information collection reflects an overall increase of 453,834 hours (currently approved 231,224) and a corresponding increase of 7,108 annual responses (currently approved 15,527). The new estimated totals are 685,058 hours and 22,635 annual responses. We attribute this adjustment to an increase in the number of EA submissions we received since the last extension.

Dated: June 1, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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